

REMARKS

Claims 15-18, 20-22 and 25-30 were pending. Claims 15-18, 20-22 and 25-30 were cancelled without prejudice. New claims 31-49 are introduced.

Support for new claim 31 can be found, *inter alia*, on page 6, lines 9-10, in example 2 on page 16 of the original specification and in the original claim 11. Support for new claims 32-37, 39-41 can be found, *inter alia*, in the original claims 15-18, 20-22, 26 and 27, respectively. Support for new claim 38 can be found, *inter alia*, in the original claim 21. Support for new claims 42, 43 and 49 can be found, *inter alia*, in the original claim 11 and in Table 1 on page 7 of the original specification. Support for new claims 43-48 can be found, *inter alia*, on page 8, line 24 to page 9, line 2. Therefore, the introduction of new claims 31-49 are fully supported by the original specification and does not raise any issue of new matter. Accordingly, entry of this Amendment is respectfully requested. Upon entry of this Amendment, claims 31-49 will be under examination.

Claim rejection under 35 U.S.C. §112, First Paragraph

Claims 11, 15-18, 20-22 and 26-28 stand rejected under 35 U.S.C. §112, first paragraph. Applicant respectfully disagree with this ground of rejection as the use of the phrase "0.3 mg or less" comply with the requirement of 35 U.S.C. §112, first paragraph and it is supported by the specification as filed. However, to expedite the prosecution of the present application, Applicant hereby cancels claims 11, 15-18, 20-22 and 26-28 and introduces new claims 31-49 which do not include the phrase "0.3 mg or less." Therefore, this ground of rejection is moot and its withdrawal is respectfully requested.

Claim rejection under 35 U.S.C. §102(b)

Claims 11, 15-18, 20-22 and 26-28 stand rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Steigerwaldt et al. The Office Action asserts that Steigerwaldt discloses, on page 1047, column 1, "administration of an anesthetic, such as procaine hydrochloride in an amount of 0.2% or 0.2 mg per injection, which is about 0.1 mg to about 0.3 mg per injection." *Office Action at 8.*

Applicant respectfully disagree with the Examiner's characterization of Steigerwaldt as teaching the injection of procaine hydrochloride. In fact, Steigerwaldt only discloses the use of "procaine hydrochloride 0.2% as a local anesthetic." Steigerwaldt does not explicitly teaches that its procaine hydrochloride is injected.

Despite of this disagreement, in an effort to expedite the prosecution of the present application, Applicant has cancelled claims 11, 15-18, 20-22 and 26-28 without prejudice and introduced new claims 31-49. Applicant contends that new claims 31-49 are not anticipated by Steigerwaldt because Steigerwaldt does not disclose each and every element of any of new claims 31-49. Specifically, Steigerwaldt does not disclose intradermal injection of bee venom and anesthetic either simultaneously or consecutively. Steigerwaldt also does not disclose the use of anesthetic and bee venom to reduce the visual analog scale of the patient by at least 57. As being disclosed in the examples contained in the specification, following a treatment protocol which involved a plurality of injections over several visits, patients experience a remarkable reduction in the pain associated with a wide diversity of conditions. Moreover, Steigerwaldt does not disclose the use of bee venom comprising about 40%-50% of melittin, or about 1.5-2.0% of hyaluronidase in dry weight, or wherein the bee venom exhibits about 40 to about 100HHU/mL of Hyaluronidase activity when diluted to 100mcg/mL, or is capable of inhibiting gelatin induced aggregation of erythrocytes of about 3-5mm/H. Therefore, Steigerwaldt does not anticipate any of the new claims 31-49. Accordingly, reconsideration and withdrawal of this ground of rejection, as it may be applied to new claims 31-49, are respectfully requested.

Claim rejection under 35 U.S.C. §103(a)

Claims 11, 26 and 27 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Steigerwaldt in view of U.S. Patent 6,029,863 or Pharmaceutical Formulary.

Applicant respectfully point out that claims 11, 26 and 27 have been cancelled without prejudice and new claims 31-49 have been introduced to clarify that the use of anesthetic and bee venom reduces visual analog scale of the patient by at least 57 as well as the use of bee venom comprising about 40%-50% of melittin, or about 1.5-2.0% of hyaluronidase in dry weight, or wherein the bee venom exhibits about 40 to about 100HHU/mL of Hyaluronidase activity when diluted to 100mcg/mL, or is capable of inhibiting gelatin induced aggregation of erythrocytes of about 3-5mm/H. Applicant submits that Steigerwaldt, U.S. Patent 6,029,863 and Pharmaceutical Formulary, either individually or in any combination, do not teach or suggest each and every element of any of the new claims 31-49. Therefore, the combination of Steigerwaldt, U.S. Patent 6,029,863 and Pharmaceutical Formulary does not render new claims 31-49 obvious under the standard of M.P.E.P.

Moreover, the present invention has achieved unexpected results of (1) using "as little as 0.1 mg to about 0.3 mg per injection to provide optimal results based on injection of an

equal amount of the venom by weight," and that "despite relatively little amount of local anesthetic use, a significant reduction in the pain associated with the bee venom treatment was realized by the patient," and (2) reducing the VAS (pain index) by at least 57. These unexpected results further support Applicant's contention that new claims 31-49 are non-obvious over the cited prior art references.

Applicant contends that new claims 31-49 overcome this ground of rejection. Accordingly, reconsideration and withdrawal of the rejection, as it may be applied to new claims 31-49, are respectively requested.

CONCLUSION

In view of the remarks and the introduction of new claims 31-49, further and favorable consideration and the issuance of a Notice of Allowance with respect to claims 31-49 are earnestly solicited.

If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that he telephone applicant's attorney at (908) 654-5000 in order to overcome any additional objections which she might have.

No fee is deemed necessary in connection with the filing of this Amendment. However, if any fees are required in connection with this Amendment, the Examiner is authorized to charge such fees Deposit Account No. 12-1095 therefor.

Dated: April 2, 2002

Respectfully submitted,

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